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European Union

FAIRS Product Specific

EU Veterinary Supplement and Medicine Import Rules

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Report Highlights:

This document is intended to serve as a starters' guide for companies wishing to export veterinary products, including vitamins and supplements having a therapeutic effect.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Brussels USEU [BE2]
[E2]

All products marketed with a therapeutic claim fall under the scope of the veterinary medicinal products legislation. Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products sets out the basic requirements for registration. This directive can be downloaded from

http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_311/l_31120011128en00010066.pdf.

Many drugs are legally not available for food-producing animals. Under the veterinary medicinal products legislation, horses are treated as food-producing animals. This implies that stringent residue testing requirements are applicable even if the product is intended for horses kept for recreational or sports purposes. This issue and also the data requirements for minor species are currently under discussion.

There are basically two registration procedures in the EU. The first one is a centralized procedure through the European Agency for the Evaluation of Medicinal Products (EMA). The guidelines for registration are published on the EMA website (<http://www.ema.eu.int/>).

Alternatively, under the mutual recognition procedure, the applicant has to choose a reference Member State where he wants to get his first approval and then later can be recognized in other Member States. The list with the contact details of the member states is available on the Heads of Agency website (HEVRA) as following: http://www.hevra.org/documents/organisational_issues/VMRF_032_01.pdf.

Furthermore, the EU association representing the animal health industry put together a brochure on the EU registration procedure, available from <http://www.ifah.be/Europe/Publications/Dossier15.pdf>.

For a complete overview of all rules governing medicinal (including veterinary) products in the European Union, please consult http://pharmacos.eudra.org/F2/site_map.htm.

Visit our website: our website www.useu.be/agri/usda.html provides a broad range of useful information on EU import rules and food laws and allows easy access to USEU reports, trade information and other practical information. E-mail: AgUSEUBrussels@fas.usda.gov